

§Appl. No. 10/078,531
Amdt. dated May 20, 2005
Reply to Office Action of, December 2, 2004

Listing of Claims:

Please amend the claims as follows:

Listing of Claims:

Claim 1 (Withdrawn) An isolated polynucleotide comprising a polynucleotide chosen from:

- (a) a polynucleotide encoding a polypeptide having at least 70% identity to a second polypeptide comprising a sequence chosen from: SEQ ID NO: 2 or fragments or analogs thereof;
- (b) a polynucleotide encoding a polypeptide having at least 95% identity to a second polypeptide comprising a sequence chosen from: SEQ ID NO: 2 or fragments or analogs thereof;
- (c) a polynucleotide encoding a polypeptide comprising a sequence chosen from: SEQ ID NO: 2 or fragments or analogs thereof;
- (d) a polynucleotide encoding a polypeptide capable of generating antibodies having binding specificity for a polypeptide comprising a sequence chosen from: SEQ ID NO: 2 or fragments or analogs thereof;
- (e) a polynucleotide encoding an epitope bearing portion of a polypeptide comprising a sequence chosen from SEQ ID NO: 2 or fragments or analogs thereof;
- (f) a polynucleotide comprising a sequence chosen from SEQ ID NO: 1 or fragments or analogs thereof;
- (g) a polynucleotide that is complementary to a polynucleotide in (a), (b), (c), (d), (e) or (f).

Claim 2 (Withdrawn) An isolated polynucleotide comprising a polynucleotide chosen from:

- (a) a polynucleotide encoding a polypeptide having at least 70% identity to a second polypeptide comprising a sequence chosen from: SEQ ID NO: 2;
- (b) a polynucleotide encoding a polypeptide having at least 95% identity to a second polypeptide comprising a sequence chosen from: SEQ ID NO: 2;

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- (c) a polynucleotide encoding a polypeptide comprising a sequence chosen from: SEQ ID NO: 2;
- (d) a polynucleotide encoding a polypeptide capable of raising antibodies having binding specificity for a polypeptide comprising a sequence chosen from: SEQ ID NO: 2;
- (e) a polynucleotide encoding an epitope bearing portion of a polypeptide comprising a sequence chosen from SEQ ID NO: 2;
- (f) a polynucleotide comprising a sequence chosen from SEQ ID NO: 1;
- (g) a polynucleotide that is complementary to a polynucleotide in (a), (b), (c), (d), (e) or (f).

Claim 3 **(Withdrawn)** The polynucleotide of claim 1, wherein said polynucleotide is DNA.

Claim 4 **(Withdrawn)** The polynucleotide of claim 2, wherein said polynucleotide is DNA.

Claim 5 **(Withdrawn)** The polynucleotide of claim 1, wherein said polynucleotide is RNA.

Claim 6 **(Withdrawn)** The polynucleotide of claim 2, wherein said polynucleotide is RNA.

Claim 7 **(Withdrawn)** The polynucleotide of claim 1 that hybridizes under stringent conditions to either

- (a) a DNA sequence encoding a polypeptide or
- (b) the complement of a DNA sequence encoding a polypeptide;
wherein said polypeptide comprises SEQ ID NO: 2, or fragments or analogs thereof.

Claim 8 **(Withdrawn)** The polynucleotide of claim 2 that hybridizes under stringent conditions to either

- (a) a DNA sequence encoding a polypeptide or
- (b) the complement of a DNA sequence encoding a polypeptide;

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wherein said polypeptide comprises SEQ ID NO: 2.

Claim 9 (Withdrawn) The polynucleotide of claim 1 that hybridizes under stringent conditions to either

- (a) a DNA sequence encoding a polypeptide or
- (b) the complement of a DNA sequence encoding a polypeptide;
wherein said polypeptide comprises at least 10 contiguous amino acid residues from a polypeptide comprising SEQ ID NO: 2, or fragments or analogs thereof.

Claim 10 (Withdrawn) The polynucleotide of claim 2 that hybridizes under stringent conditions to either

- (a) a DNA sequence encoding a polypeptide or
- (b) the complement of a DNA sequence encoding a polypeptide;
wherein said polypeptide comprises at least 10 contiguous amino acid residues from a polypeptide comprising SEQ ID NO: 2.

Claim 11 (Withdrawn) A vector comprising the polynucleotide of claim 1, wherein said DNA is operably linked to an expression control region.

Claim 12 (Withdrawn) A vector comprising the polynucleotide of claim 3, wherein said DNA is operably linked to an expression control region.

Claim 13 (Withdrawn) A host cell transfected with the vector of claim 11.

Claim 14 (Withdrawn) A host cell transfected with the vector of claim 12.

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Claim 15 (Withdrawn) A process for producing a polypeptide comprising culturing a host cell according to claim 13 under conditions suitable for expression of said polypeptide.

Claim 16 (Withdrawn) A process for producing a polypeptide comprising culturing a host cell according to claim 14 under condition suitable for expression of said polypeptide.

Claim 17 (Currently Amended) An isolated polypeptide comprising a polypeptide which is:

- (a) a polypeptide having at least 70% identity to a second polypeptide having an amino acid sequence comprising: SEQ ID NO: 2, or fragments comprising at least ten contiguous amino acids thereof;
- (b) a polypeptide having at least 95% identity to a second polypeptide having an amino acid sequence comprising: SEQ ID NO: 2, or fragments comprising at least ten contiguous amino acids thereof;
- (c) a polypeptide comprising a sequence chosen from SEQ ID NO: 2, or fragments comprising at least ten contiguous amino acids thereof;
- (d) a polypeptide capable of generating antibodies having binding specificity for a polypeptide having a sequence chosen from SEQ ID NO: 2, or fragments comprising at least ten contiguous amino acids thereof;
- (e) an epitope bearing portion of a polypeptide having a sequence chosen from SEQ ID NO: 2, or fragments comprising at least ten contiguous amino acids thereof;
- (f) the polypeptide of (a), (b), (c), (d), or (e) wherein the N-terminal Met residue is deleted; or
- (g) the polypeptide of (a), (b), (c), (d), (e), or (f) wherein the secretory amino acid sequence is deleted,

wherein said polypeptide elicits antibodies specific for BVH-P7 of S. pyogenes.

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Claim 18 (Currently Amended) An isolated polypeptide comprising a polypeptide which is:

- (a) a polypeptide having at least 70% identity to a second polypeptide having an amino acid sequence comprising: SEQ ID NO: 2;
- (b) a polypeptide having at least 95% identity to a second polypeptide having an amino acid sequence comprising: SEQ ID NO: 2;
- (c) a polypeptide comprising a sequence chosen from SEQ ID NO: 2
- (d) a polypeptide capable of generating antibodies having binding specificity for a polypeptide having a sequence chosen from SEQ ID NO: 2;
- (e) an epitope bearing portion of a polypeptide having a sequence chosen from SEQ ID NO: 2;
- (f) the polypeptide of (a), (b), (c), (d), or (e) wherein the N-terminal Met residue is deleted; or
- (g) the polypeptide of (a), (b), (c), (d), (e), or (f) wherein the secretory amino acid sequence is deleted,

wherein said polypeptide elicits antibodies specific for BVH-P7 of S. pyogenes.

Claim 19 (Currently Amended) A chimeric polypeptide comprising two or more polypeptides having a sequence chosen from SEQ ID NO: 2, ~~or fragments comprising each of~~ at least ten contiguous amino acids thereof; provided that the polypeptides are linked to form a chimeric polypeptide, wherein said chimeric polypeptide elicits antibodies specific for BVH-P7 of S. pyogenes.

Claim 20 (Currently Amended) A chimeric polypeptide comprising two or more polypeptides, wherein at least one polypeptide having comprises an amino acid sequence of at least ten contiguous amino acids chosen from SEQ ID NO: 2; provided that the polypeptides are linked to form a chimeric polypeptide, wherein said chimeric polypeptide elicits antibodies specific for BVH-P7 of S. pyogenes.

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Claim 21 (Previously Presented) A pharmaceutical composition comprising a polypeptide according to claim 17 and a pharmaceutically acceptable carrier, diluent or adjuvant.

Claim 22 (Withdrawn) A method for prophylactic or therapeutic treatment of pharyngitis, erysipelas and impetigo, scarlet fever, and invasive diseases such as bacteremia and necrotizing fasciitis in a host susceptible to pharyngitis, erysipelas and impetigo, scarlet fever, and invasive diseases such as bacteremia and necrotizing fasciitis and also toxic shock comprising administering to said host a prophylactic or therapeutic amount of a composition according to claim 21.

Claim 23 (Withdrawn) A method for prophylactic or therapeutic treatment of *Streptococcus pyogenes* bacterial infection in a host susceptible to *Streptococcus pyogenes* infection comprising administering to said host a prophylactic or therapeutic amount of a composition according to claim 21.

Claim 24 (Withdrawn) A method according to claim 22 wherein the host is an animal.

Claim 25 (Withdrawn) A method according to claim 22 wherein the host is a human.

Claim 26 (Withdrawn) A method for diagnostic of streptococcal infection in a host susceptible to streptococcal infection comprising

- (a) obtaining a biological sample from a host;
- (b) incubating an antibody or fragment thereof reactive with a streptococcal polypeptide of claim 17 with the biological sample to form a mixture; and
- (c) detecting specifically bound antibody or bound fragment in the mixture which indicates the presence of streptococcal.

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Claim 27 (Withdrawn) A method for detection of antibody specific to streptococcus antigen in a biological sample comprising

- (a) obtaining a biological sample from a host;
- (b) incubating one or more streptococcal polypeptides of claim 17 or fragments thereof with the biological sample to form a mixture; and
- (c) detecting specifically bound antigen or bound fragment in the mixture which indicates the presence of antibody specific to streptococcus.

Claim 28 (Withdrawn) A method of preparing a pharmaceutical composition for the prophylactic or therapeutic treatment of streptococcal infection comprising combining a polypeptide according to claim 17 with a pharmaceutically acceptable carrier, diluent or adjuvant.

Claim 29 (Withdrawn) A kit for detection or diagnosis of streptococcal infection comprising a polypeptide according to claim 17, and instructions for use of the polypeptide in the detection or diagnosis of streptococcal infection.

Claim 30 (Previously Presented) A pharmaceutical composition comprising a polypeptide according to claim 18 and a pharmaceutically acceptable carrier, diluent or adjuvant.

Claim 31 (Withdrawn) A method for diagnostic of streptococcal infection in a host susceptible to streptococcal infection comprising

- (d) obtaining a biological sample from a host;
- (e) incubating an antibody or fragment thereof reactive with a streptococcal polypeptide of claim 18 with the biological sample to form a mixture; and
- (f) detecting specifically bound antibody or bound fragment in the mixture which indicates the presence of streptococcal.

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Claim 32 (Withdrawn) A method for detection of antibody specific to streptococcus antigen in a biological sample comprising
(a) obtaining a biological sample from a host;
(b) incubating one or more streptococcal polypeptides of claim 18 or fragments thereof with the biological sample to form a mixture; and
(c) detecting specifically bound antigen or bound fragment in the mixture which indicates the presence of antibody specific to streptococcus.

Claim 33 (Withdrawn) A method of preparing a pharmaceutical composition for the prophylactic or therapeutic treatment of streptococcal infection comprising combining a polypeptide according to claim 18 with a pharmaceutically acceptable carrier, diluent or adjuvant.

Claim 34 (Withdrawn) A kit for detection or diagnosis of streptococcal infection comprising a polypeptide according to claim 18, and instructions for use of the polypeptide in the detection or diagnosis of streptococcal infection.

Claim 35 (Previously Presented) An isolated polypeptide of claim 17, which comprises at least one epitope that elicits antibodies specific for *S. pyogenes*.

Claim 36 (Previously Presented) An isolated polypeptide of claim 18, which comprises at least one epitope that elicits antibodies specific for *S. pyogenes*.

Claim 37 (Previously Presented) An isolated polypeptide of claim 17, having at least 95% identity to a second polypeptide having an amino acid sequence comprising: SEQ ID NO: 2, or fragments thereof comprising at least ten contiguous amino acids.

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Claim 38 (Previously Presented) An isolated polypeptide of claim 17 which is SEQ ID NO:2, or fragments thereof comprising at least ten contiguous amino acids.

Claim 39 (Previously Presented) An isolated polypeptide of claim 19, having at least 95% identity to a second polypeptide having an amino acid sequence comprising: SEQ ID NO: 2.

Claim 40 (Previously Presented) An isolated polypeptide of claim 19, which is SEQ ID NO:2.

Claim 41 (Previously Presented) An isolated BVH-P7 polypeptide from a *S. pyogenes* strain comprising at least 90% amino acid sequence identity to SEQ ID NO:2, or fragments thereof comprising at least ten contiguous amino acids thereof, and wherein said polypeptide comprises at least one epitope that elicits antibodies specific for *S. pyogenes*.

Claim 42 (Previously Presented) An isolated polypeptide of claim 17, wherein said polypeptide hybridizes to SEQ ID NO:1 under stringent conditions.

Claim 43 (New) An isolated polypeptide of claim 1, comprising a polypeptide which is:

- (a) a polypeptide comprising at least 70% identity along its entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO:2;
- (b) the polypeptide of (a), wherein the N-terminal Met residue is deleted; or
- (c) the polypeptide of (a) or (b), wherein the secretory amino acid sequence is deleted, wherein said polypeptide is capable of eliciting an immune response specific to BVH-P7 of *S. pyogenes*.

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Claim 44 (New) An isolated polypeptide of claim 1, comprising a polypeptide which is:

- (a) a polypeptide comprising at least 90% identity along its entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO:2;
- (b) the polypeptide of (a), wherein the N-terminal Met residue is deleted; or
- (c) the polypeptide of (a) or (b), wherein the secretory amino acid sequence is deleted.

Claim 45 (New) An isolated polypeptide of claim 1, comprising a polypeptide which is:

- (a) a polypeptide comprising at least 95% identity along its entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO:2;
- (b) the polypeptide of (a), wherein the N-terminal Met residue is deleted; or
- (c) the polypeptide of (a) or (b), wherein the secretory amino acid sequence is deleted, wherein said polypeptide is capable of eliciting an immune response specific to BVH-P7 of *S. pyogenes*.